

HEINZ et al.
S.N. 09/980,468
OA January 27, 2006

REMARKS:

Claims 1, 4-5, 8-12 and 24-29 are currently pending. Claim 1 is amended.

Claim Rejections 35 USC § 112 ¶1

Claims 1, 4-5, 8-12 and 24-29 are rejected for allegedly failing to comply with the written description requirement. The Examiner has maintained this rejection contrary to our arguments asserting that a representative number of compounds have been disclosed. Moreover, the Examiner believes that the rejected Claims also fail to comply with the enablement requirement because the instant Specification does not provide clear evidence as to which sequences are used in the examples of the instant application.

In regards to all the 112 ¶1 rejections, it must be remembered that to satisfy the written description prong of 35 USC §112 ¶1, the Specification must only describe the invention in sufficient detail so that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). No particular form of disclosure is required, but "the description must clearly allow persons of ordinary skill in the art to recognize that [the patentee] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) (citing *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976)).

The Claims are written in such a manner that the problems of insufficient numbers of examples as described by the Examiner in the Office Action should not apply. Applicants' invention is drawn to an isolated acid sequence which codes for a polypeptide having $\Delta 6$ -acetylenase and/or $\Delta 6$ -desaturase activity. The MPEP states that a "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces" and as such, a single species may be enough to identify the entire genus (see MPEP 2163.II.A.3.a.ii.). A recent Federal Circuit case supports the statements of the MPEP. When discussing what is required for a written description the court said "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution" (*Capon v. Eshhar*, 418 F.3d 1349, 1358; 2005). Further, in overturning a BPAI decision, which relied on similar rejections reasons as stated in

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the instant Office Action, where both parties to an interference had all Claims in their respective patents cancelled for failing to meet the written description requirement, the court stated that "[t]he Board erred in refusing to consider the state of the art of the scientific knowledge" and when citing *Lilly* and *Fiers* spoke of a rulings in view of a "wish" list provided in said inventions, and not the state of the relevant art (*Id.* at 1357). Further, the court stated, that "[i]t is not necessary that every permutation with a generally operable invention be effective in order for an inventor to obtain a generic claim" and both parties were lauded because they "present[ed] not only general teachings... but also specific examples" (*Id.* at 1359).

Applicants assert that the instant Specification fully complies with all the aforementioned requirements because it allows one of ordinary skill in the art to practice the instant invention. Applicants provide in the instant Specification summary information such as the function of polyunsaturated fatty acids and general molecular biology techniques which meet the "general teachings" prong. Further, Applicants have supplied "specific examples" of the instant invention as required of the second prong of *Capon*. The instant Specification teaches at least the nucleic sequences, SEQ ID NO: 1, SEQ ID NO: 3 and SEQ ID NO: 11, and at least the amino acid sequence, SEQ ID NO: 2 as well as teaching the Cer proteins. Thus while not required to provide even a single working example (*See, In re Gosteli* above - no specific form of the disclosure is required), Applicants have provided such examples as set forth above.

Moreover, according to accepted principles of patent practice Applicants are not merely entitled to the literally disclosed invention. If that were the case then the scope of protection would be limited to the disclosed examples. However, Applicants are rather entitled to the whole range of embodiments which is made accessible by their invention and which is properly claimed therein. Consequently, Applicants urge that the instant invention has been sufficiently disclosed, sufficiently supported by experimental data and thus, provides sufficient written description for the entire genus based on the applicable standards. Therefore, Applicants respectfully urge that the Examiner has mistakenly applied a too strict an interpretation for claiming a genus and that Applicants are entitled to claim additional embodiments which are not represented by individual examples, i.e. the genus form the species recited.

Accordingly, for at least the reasons described above, the instant Application does provide an adequate written description for one of ordinary skill in the art to practice the instant invention and withdrawal of the instant rejections is respectfully requested. The instant

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Specification in combination with what would have been known by a skilled artisan at the time of filing, provides sufficient written description support to clearly conclude that the inventor "at the time the application was filed, had possession of the claimed invention." Favorable action is solicited.

Regarding the enablement requirement of §112, the Federal Circuit has held that "[t]he specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation'." (*Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. (2003))). The Claims, as currently amended, are fully enabled by the Specification of the instant application in combination with the general knowledge of one of ordinary skill in the art.

The Examiner has dismissed Applicants' previous arguments stating that they are not persuasive. Applicants reassert all of their prior arguments and since the only reason provided for said unpersuasiveness is because it is alleged that the instant examples are unclear, respectfully request withdrawal of the instant rejections. Applicants note that there is no requirement for examples in an application for a United States Letter Patent. Further, Applicants' previous arguments stating that methods for transforming organism, the disclosure of vectors, the creation of transformed plants and the extraction of oil provide the basis to show that the instant application is sufficiently enabled for one of ordinary skill in the art to practice.

Applicants respectfully submit that for at least the reasons listed above the rejections under 35 USC §112, first paragraph, written description and enablement should be withdrawn and an indication of allowance should appear in the next paper from the Office. Favorable action is solicited.

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